REMARKS

Claims 6-8 have been cancelled as directed to a non-elected invention. Applicants reserve the right to file one or more divisional applications for these claims. Claim 1 has been amended. Claims 1-5 and 9-10 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Pierre, et al. (Journal of Clinical Microbiology, 1991, 29(4): 712).

The Examiner interprets the gel electrophoresis and transfer to nitrocellulose as taught by Pierre, et al. as equivalent to "gel filtration" and "collecting a fraction containing nucleic acids" as claimed.

It is respectfully submitted that gel filtration is not a type of electrophoresis. Gel filtration relies upon separation on the basis of size, not charge as in electrophoresis. Furthermore, gel filtration is performed using a column packed with beads with the sample in the liquid phase, not in a gel, with the sample moving through the gel in response to the applied charge (see Outlines of Biochemistry, 4th ed. (Conn & Stumpf), 1976, pages 598-599, Attachment A). Accordingly, Pierre, et al. do not teach gel filtration as claimed.

In order to add further clarity, Applicants have amended claim 1 to recite "collecting a solution of a fraction containing nucleic acids". Clearly Pierre, et al. do not teach collection of the sample in a solution as Pierre, et al. are directed to the use of gel electrophoresis, a technique separate from gel filtration as discussed above, where the nucleic acids are isolated from the gel by transfer to a nitrocellulose membrane.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 1-5 and 9-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Burdick, et al. (EP 0393744) in view of Akane, et al. (Biotechniques (1994) 16(2): 235).

Burdick, et al. do not teach gel filtration. However, the Examiner asserts that it would be obvious to use gel filtration in view of the teaching of Akane, et al. who teach gel filtration to eliminate contaminants and degraded templates.

Applicants respond that none of the cited references teach or suggest incorporating a gel filtration step into a series of steps for isolating and purifying nucleic acids from biological samples where the use of organic solvents and repeated centrifugation steps are avoided.

The claimed method is based upon the use of a salt or salts to disrupt binding between DNAs and binding between DNA and proteins in order to extract the DNA from the cellular material and the DNA-protein complexes without the use of organic solvents such as ethanol and phenol/chloroform extraction and without repeated centrifugation steps as discussed in the specification at page 2, paragraph 2 to page 3, paragraph 1. Although the method relies upon the salt to extract the DNA, the presence of the salt is a hindrance when subsequently performing the PCR reaction. Although Burdick, et al. teach the use of heat and salt to extract the DNA as pointed out by the Examiner (col. 14, lines 35-40). Burdick, et al do not address the problem of removal of the salt after the DNA extraction and before performing PCR. This technical problem is addressed by Applicants by the use of a gel filtration step to desalt the sample so that PCR can be performed successfully. The filter taught by Burdick, et al. (col. 14, lines 41-44) will not remove salt so the resulting samples of Burdick, et al. will be hindered by the presence of the salt from the extraction process when performing PCR reactions.

Although Akane, et al. teach the use of a gel filtration column before performing PCR, Akane, et al. use a conventional method of DNA extraction using phenol/chloroform extraction (see first paragraph of Akane, et al.). Accordingly, there is no recognition in Akane, et al. of the importance of removing salt when salt is used to extract DNA from a sample because Akane, et al. use phenol/chloroform to extract the DNA, not salt and heat. As discussed above, Burdick, et al. also do not address this problem.

According to the method of the claimed invention, nucleic acids suitable for PCR can be isolated more rapidly and easily from a sample containing contaminants such as PCR inhibitory substances. The method as claimed is not taught by the cited references, taken separately or together.

In view of Applicants' arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee. Application in **bold** corresponds to the above-referenced application.

Serial Number	Title	Filed
09/817,251	METHOD FOR STIRRING LIQUIDS	03/27/01
10/466,453	QUANTITATIVE ANALYZING METHOD AND QUANTITATIVE ANALYZER USING SENSOR	12/02/03
10/481,397	INFORMATION COMMUNICATION SYSTEM	12/19/03
10/483,205	ADJUSTABLE LANCING DEVICE	01/07/04
10/493,919	TEST APPARATUS	04/27/04
10/862,465	METHOD AND IMPLEMENT FOR OPENING HOLE IN SOFT MATERIAL	06/08/04
10/498,782	SAMPLE MEASURING DEVICE	06/10/04
10/533,601	ANALYTICAL TOOL	04/29/05
10/545,852	METHOD OF DETECTING CHLAMYDIA TRACHOMATIS AND KIT THEREFOR	08/17/05
10/547,354	DNA AMPLIFICATION METHOD AND KIT THEREFOR	08/29/05
11/220,622	SUPPLEMENT FOOD FOR LOW BLOOD GLUCOSE RECOVERY	09/08/05

10/553,576	METHOD OF DETECTING OR QUANTITATIVELY DETERMINING MITOCHONDRIAL DNA 3243 VARIATION, AND KIT THEREFOR	10/17/05
10/536,822	METHOD AND APPARATUS FOR CONCENTRATION AND PURIFICATION OF NUCLEIC ACID	10/18/05
10/553,509	METHOD OF DETECTING B3 ADRENALINE RECEPTOR MUTANT GENE AND NUCLEIC ACID PROBE AND KIT THEREFOR	10/18/05
10/553,614	METHOD OF DETECTING PANCREATIC ISLET AMYLOID PROTEIN MUTANT GENE AND NUCLEIC ACID PROBE AND KIT THEREFOR	10/18/05
10/553,376	**METHOD OF ISOLATING NUCLEIC ACIDS, AND KIT AND APPARATUS FOR NUCLEIC ACID ISOLATION**	**10/19/05**
10/536,829	DEVICE FOR PRETREATING SPECIMEN	10/31/05
10/550,671	PROCESS FOR PRODUCING GLUCOSE DEHYDROGENASE	11/09/05
11/587,333	MUTANT GLUCOSE DEHYDROGENASE	10/19/06
11/712,307	METHOD FOR DETECTING TARGET NUCLEIC ACID	02/27/07
11/665,296	MUTANT GLUCOSE DEHYDROGENASE	04/13/07

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 20, 2007

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Attachment A

OUTLINES OF BIOCHEMISTRY

FOURTH EDITION

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The reverse procedure may be used for DEAE columns, namely placing protein on a DEAE column at pH 8 and eluting by decreasing pH or increasing salt concentration or both.

A.2.9 Gel Filtration

The technique of separating molecules of different size by passage through a gel column is called gel filtration. A polysaccharide, dextran, is carefully cross-linked to give small beads of a hydrophilic, insoluble nature which when placed in water swells considerably to form an insoluble gel. The commercial name for the gel is *Sephadex*. The property of Sephadex to exclude solutes of large molecular size, and to be accessible for diffusion to molecules of small dimension is the basis of the separation method.

The general expression for the appearance of a solute in an effluent is

$$V = V_0 + K_D V_i$$

where V is the elution volume of a substance with a given K_D, V_0 is the void volume or the total volume of the external water (outside the gel grain), V_i is the internal water volume in the gel grain, and K_D is the distribution coefficient for a solute between the water in the gel grain and the surrounding water. A substance with K_D of zero is completely excluded from the gel beads, and substances with K_D values between 0 and 1 are partially excluded. If a sample containing a solute with a $K_D = 1$ and another with $K_D = 0$ is introduced in the column, the latter will appear in the effluent after a volume V_0, and the former will appear after a volume $V_0 + K_D V_i$.

The procedure of dialysis can be readily carried out on a suitable Sephadex column. The column is first equilibrated with the new buffer. The protein solution is introduced to the top of the column and eluted with the new buffer. When the volume V_0 has passed, the protein is eluted in the new buffer medium while the original buffer and small-molecular-weight compounds, etc., are eluted after a volume of $V_0 + K_D V_i$. The process is very rapid and hence is especially useful when working with labile proteins. Since K_D varies with proteins of different molecular weights, it is possible to fractionate proteins on gel filtration. The biochemist has a choice of several types of Sephadex beads to prepare columns for this procedure. Thus, Sephadex G-25 excludes compounds of molecular weight of 3500–4500, Sephadex G-50, 8000–10,000, and Sephadex G-75, 40,000–50,000. Sephadex G-100 and G-200 gels may be used for higher-molecular-weight proteins. Figure A-2-2 gives some typical separation results.

An equally useful application of column gel filtration is its use as a method to determine molecular weights, even if the protein has not been extensively purified. Depending on the possible molecular weight of the protein, a suitable gel is chosen. Usually, Sephadex G-100 or G-200 is selected, a column is carefully prepared, and the elution volumes of pure proteins with known molecular weights and stabilities are determined to establish a calibration curve. The protein whose molecular weight is to be determined is placed on the same column and its elution volume is determined under conditions identical to those used to elute the known proteins. The results are plotted, K_D vs log mol wt, as depicted in Figure A-2-3.

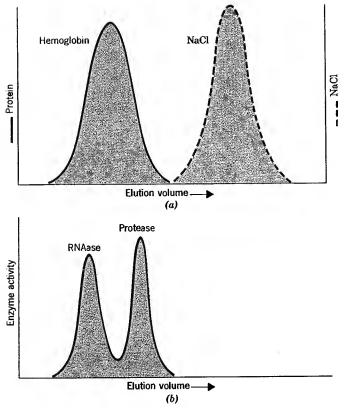

Figure A-2-2

Typical elution patterns of (a) a dialysis on Sephadex G-25 to separate hemoglobin from salt; and (b) to show separation of RNAase from a protease in pancreatic extract employing a Sephadex G-75 column.

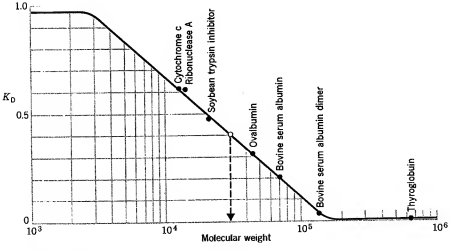

Figure A-2-3

Relationship between K_D and the logarithm of the molecular weight of proteins as determined by column gel filtration on Sephadex G-150.